UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
	)	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO:	)	Hon. Patti Saris
United States of America ex rel. Ven-a-Care of the Florida Keys, Inc., v. Abbott Laboratories, Inc., and Hospira, Inc. CIVIL ACTION NO. 06-11337-PBS	)	

UNITED STATES' OPPOSITION TO
ABBOTT LABORATORIES, INC.'S MOTION TO DISMISS

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I. INTRODUCTION

The United States has sued Abbott Laboratories, Inc. ("Abbott") under the False Claims Act ("FCA") and the common law for engaging in the following misconduct: (1) reporting inflated prices to price reporting compendia relied upon by Medicare and Medicaid to set reimbursement, (2) supplying those inflated prices to create artificially large profit margins or "spreads" between Medicare and Medicaid reimbursement and the purchase price of Abbott's drugs, (3) marketing the inflated spreads to customers as an inducement to purchase Abbott's drugs, and (4) withholding information and/or purposely providing misleading information that was critical to government decisions regarding amounts to pay on claims for Abbott's products.

By doing so, Abbott caused false or fraudulent claims to be submitted by (1) engaging in a fraudulent course of conduct that caused false or fraudulent claims to be submitted to the federal government, (2) offering illegal inducements prohibited by the Anti-kickback Statute ("AKS") that caused false or fraudulent claims to be submitted for Abbott drugs, and (3) submitting false statements to get false Medicare and Medicaid claims paid.

In its motion to dismiss, Abbott asserts two overarching arguments. *First*, Abbott argues that it cannot be found liable under the FCA and common law due to insufficient statutory and regulatory guidance on the pricing terms at issue. *Second*, Abbott contends that the United States' efforts to evaluate the efficiency and potential abuse of government drug reimbursement programs generally – as memorialized in the various reports Abbott improperly submits with its motion – somehow legitimized Abbott's abuse of those programs. Abbott then asks the Court to conclude that the United States invited and embraced Abbott's fraudulent conduct as set forth in the Complaint. These arguments are meritless.

First, no extra statutory or regulatory definition of the pricing terms at issue is required to establish that the prices reported by Abbott cannot – under any reasonable interpretation – be considered the prices at which Abbott was typically selling the drugs identified in the Complaint. For example, the Complaint alleges that Abbott knowingly reported a direct price ("DP") of $64.35 for Vancomycin in 1999, while the actual market price was closer to $5.[1] Abbott knew that its false price reporting would inflate reimbursement for its products; Abbott's own Manager for Reimbursement advised that "[h]aving a published [price] that is high allows a provider to bill at that list price." Complaint at ¶ 66.

Second, the reports Abbott attaches to its Motion to Dismiss are an attempt to distract the Court from the specific misconduct set forth in the Complaint. The United States never "embraced" Abbott's false price reporting and marketing practices as Abbott suggests in its Memorandum of Law in Support of Its Motion to Dismiss ("Memorandum of Law"). The United States never sanctioned Abbott's manipulation of Abbott's reported prices nor permitted public funds to be used to pay illegal remuneration to Abbott's customers.

For the reasons set forth more fully below, the United States respectfully asks this Court to deny Abbott's Motion to Dismiss in its entirety.

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[1] For certain drugs, Abbott reported inflated "List Prices" or "Direct Prices" (both referred to hereinafter as "DP") to the price reporting compendia relied upon by the Medicare and Medicaid programs. Complaint at ¶ 59. A DP is supposed to reflect the price paid by a customer that buys drugs directly from Abbott and not through a wholesaler. *Id*. One of the key price reporting compendia – First Databank's *Blue Book*, which provided pricing information for the vast majority of the state Medicaid programs – calculated Abbott's Average Wholesale Prices ("AWPs") by applying a markup – usually 18.75% – to Abbott's DPs during the relevant time period. *Id*. at ¶ 60. Abbott knew – and knew how – its DPs were used to set the *Blue Book* AWPs used by state Medicaid programs.

II. ARGUMENT

In evaluating a motion to dismiss for failure to state a claim, the Court must accept the facts alleged in the Complaint, draw all reasonable inferences therefrom in the plaintiff's favor, and determine whether the complaint, so read, sets forth facts sufficient to justify recovery on any cognizable theory.[2] *TAG/ICIB Services, Inc. v. Pan American Grain Co., Inc.*, 215 F.3d 172, 175 (1st Cir. 2000); *LaChapelle v. Berkshire Life Ins. Co.*, 142 F.3d 507, 508 (1st Cir. 1998). Only if there is no theory on which the United States could prevail should the Complaint be dismissed. *See TAG/ICIB Services, Inc.*, 215 F.3d at 175.

The Complaint amply sets forth facts to support several theories on which the United States may prevail. As the Complaint alleges, Abbott engaged in a fraudulent scheme that

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[2] Abbott attaches with its Motion to Dismiss an appendix of 31 government reports relating to drug pricing. Abbott appends these reports primarily to argue that it lacked the requisite FCA scienter for its false price reporting due to some government knowledge of general problems with AWP-based reimbursement systems.

"Ordinarily, a court may not consider any documents that are outside of the complaint, or not expressly incorporated therein, unless the motion is converted into one for summary judgment." *Alternative Energy, Inc. v. St. Paul Fire and Marine Ins. Co.*, 267 F.3d 30, 33 (1st Cir. 2001), *citing*, *Watterson v. Page*, 987 F.2d 1, 3 (1st Cir.1993). Courts can take judicial notice of "matters of public record" on a motion to dismiss. *Boateng v. InterAmerican University, Inc.*, 210 F.3d 56, 60 (1st Cir. 2000).

Yet, almost none of the reports constitutes the kind of legislative or regulatory public record that should be considered when deciding a motion to dismiss, certainly not as it reflects Abbott's scienter. *See* May 22, 2006 Motion to Dismiss California's State FCA Case Hearing Transcript at 31 (the Court notes that only matters of public record, such as legislative or regulatory history, may be considered on a motion to dismiss). This Court should not consider the reports Abbott has submitted when ruling on Abbott's motion to dismiss. *See generally* Plaintiffs' Objections Pursuant to Rule 201(e) of the Federal Rules of Evidence to Judicial Notice of Facts and Conclusions Set Forth in Defendants' Motion to Dismiss," filed March 3, 2006, in *State of California ex rel Ven-A-Care v. Abbott Laboratories, et al*, 03-CV-11226-PBS, (Docket #s 2185 and 2432). Regardless, as discussed *infra* in Section I(A)(3), these reports are irrelevant to (1) the United States' Abbott-related claims and (2) the legal theories at issue in this matter.

caused the Medicare and Medicaid programs to pay excessive reimbursement to Abbott's customers, *e.g.*, pharmacies, physicians, hospitals, home health agencies, nursing homes, home infusion companies, clinics and physicians. In furtherance of this scheme, Abbott reported false, fraudulent and inflated drug prices for certain drugs (listed in the Complaint at ¶¶ 31 and 35) to several price reporting compendia that the Medicare and Medicaid programs relied upon to set reimbursement rates for Abbott's customers.

These false and fraudulent reported prices are a component of the claims process since the government uses these prices to calculate reimbursement for Abbott's drugs. Complaint at ¶¶ 39-50. Abbott knew that the Medicare and Medicaid programs relied on Abbott's reported prices to those compendia to set reimbursement rates for claims submitted for Abbott's drugs. Complaint at ¶ 66. Abbott sold the drugs at far lower prices, and marketed the government-funded "spread" between the inflated reimbursement amounts and the actual acquisition costs of the drugs to existing and potential customers so as to increase its sales and profits. Complaint ¶¶ 55, 63, 66.

The United States alleges that Abbott thereby engaged in a fraudulent course of conduct that (1) resulted in a major financial loss to the United States and (2) gives rise to liability under 31 U.S.C. § 3729(a)(1) and (2). Complaint at ¶¶ 102-107 (First and Second Causes of Action). These allegations adequately state a claim under the FCA. *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968) (the FCA "was intended to reach all types of fraud, without qualification, that might result in a financial loss to the Government."); *United States ex rel. Hendow v. University of Phoenix*, 2006 WL 2530394 at *5 (9th Cir. September 5, 2006) (FCA liability extends to false course of conduct meant to influence claims paid by government);

United States ex rel. Franklin v. Parke-Davis, 2003 WL 22048255 (D. Mass. 2003) (off-label promotion scheme could give rise to FCA liability); *United States v Raymond & Whitecomb Co.*, 53 F. Supp. 2d 436, 445 (S.D.N.Y. 1999) (FCA violated when "'one who engages in a fraudulent course of conduct that causes the government' to lose money by honoring a false claim."), *quoting*, *United States v. Incorporated Village of Island Park*, 888 F.Supp. 419, 439 (S.D.N.Y.1995).

In addition, the United States alleges that Abbott is liable under the FCA for offering illegal remuneration to its customers – in the form of artificially large spreads that led to inflated government reimbursement for Abbott drugs – in violation of the Anti-kickback Statute. Again, it is clear that these allegations adequately state a claim under the FCA. *See, e.g.*, *United States ex rel. Thompson v. Columbia Healthcare Corp*, 125 F.3d 899 (5th Cir. 1997) (violation of AKS can give rise to FCA liability); *United States ex rel. Pogue v. Diabetes Treatement Centers of America*, 238 F. Supp. 2d 258 (D.D.C. 2002) (same).

The United States also asserts a claim for the recovery of monies by which Abbott has been unjustly enriched through its price fraud scheme, including profits earned by Abbott because of illegal inducements Abbott arranged to be paid to its Customers. Complaint at ¶¶ 108-111 (Third Cause of Action). Finally, the United States alleges that Abbott is liable for common law fraud because it made material and false representations concerning the prices of its drugs with knowledge of their falsity or reckless disregard for the truth and with the intention that the United States act upon the misrepresentations to its detriment. Complaint at ¶¶ 112-115 (Fourth Cause of Action). As discussed below, both causes of actions are adequately pled in the Complaint.

A. The FCA Causes of Action State A Claim Upon Which Relief May Be Granted.

1. The Claims at Issue Are False.

Abbott contends that the United States has not pled the falsity element of its FCA claims because: (1) the claims are not false on their face, (2) the falsity is not adequately alleged, (3) Congress did not intend Average Wholesale Price ("AWP") to reflect acquisition costs, and (4) AWP is an ambiguous concept that cannot give rise to falsity under the FCA. These arguments lack merit.

a. The Claims at Issue Need Not Be False on Their Face to Give Rise to FCA Liability.

Abbott argues (1) that the government has not alleged that there were claims filed and (2) that the claim forms that were filed were not false because the allegedly false prices do not appear on those claim forms. Abbott Laboratories, Inc.'s Memorandum of Law in Support of its Motion to Dismiss ("Memorandum of Law") at 15-17. These arguments both contradict themselves and lack merit.

Citing *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 225 (1st Cir. 2004) and *United States v. Rivera*, 55 F.3d 703 (1st Cir. 1995), Abbott argues that the Complaint should be dismissed because it only alleges a fraudulent scheme and does not tie that scheme to the submission of claims. Abbott is simply wrong; the United States alleged that claims were filed throughout its Complaint. *See* Complaint at ¶¶ 4, 6, 33-34, 37, 51, 58, 66, 82, 101, 103-104, 106. By contrast, in *Karvelas*, the relator in that case did not tie the alleged scheme to the submission of claims. *See* 360 F.3d at 234-35 ("While Karvelas does describe the procedures allegedly used by the hospital to submit false claims to the United States, the alleged

existence of such procedures does not permit us to speculate that false claims were in fact submitted"). Abbott's reliance on *Rivera* is misplaced. That case focused on whether certain reimbursement applications "had the practical effect of inducing payment in a sufficiently 'immediate' manner" to be considered claims under the FCA, not whether a claim was actually submitted. *Rivera*, 55 F.3d at 709-712. Similarly, Abbott's reliance on *United States v. Southland Mgmt. Corp.*, 326 F.3d 669 (5th Cir. 2003) (*en banc*), is unpersuasive since that case related to the falsity of claims, not whether claims were actually submitted. *Id.* at 674-75.

Abbott's second argument misconstrues both FCA law generally and the fundamental nature of this FCA case. Abbott argues that the FCA is so narrow that it contemplates only those instances where a claim is "false on its face." Memorandum of Law at 16. As Congress observed in adopting the 1986 amendments to the FCA, "a false claim may take many forms," including billing for "services not provided, or provided in violation of contract terms, specification, statute or regulation," or "fraudulently cashing a Government check, which was wrongfully or mistakenly obtained." S. Report 99-345, 1986 U.S.C.C.A.N. 5266, at *5274 (July 28, 1986). Likewise, the Supreme Court, the First Circuit and this Court have sustained FCA liability where no falsity was apparent on the face of the specific claims. *See United States ex rel. Marcus v. Hess*, 317 U.S. 537, 543-45 (1943) (collusive bid-rigging at outset of project made all requests for payment fraudulent); *Rivera*, 55 F.3d at 706 (although "from Merrill Lynch's perspective, the claim it presented may not have been 'false or fraudulent,' that claim was inflated by defendants' earlier fraud; and the case law allows the United States, in such circumstances, to sue defendants under the FCA for having 'caused' the filing of a 'false' claim against the government."); *Parke-Davis,* 2003 WL 22048255 (sustaining FCA case based on fraudulent off-label marketing scheme

which rendered related claims ineligible for payment); *United States ex rel. Kneepkins v. Gambro Healthcare*, 115 F. Supp. 2d 35, 43 (D. Mass. 2000) (upholding FCA claims based on an underlying violation of the AKS despite no falsity on face of claim).

The FCA addresses claims that are both "false" and "fraudulent." *See* 31 U.S.C. § 3729(a)(1) and (2) (liability arises for person who (1) knowingly causes to be presented "false or fraudulent claim(s)" or (2) "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid."). Indeed, the FCA "was intended to reach all types of fraud, without qualification, that might result in a financial loss to the Government." *Neifert-White Co.*, 390 U.S. at 232; *Hendow*, 2006 WL 2530394 at *3 (noting that "Congress emphasized that the scope of false or fraudulent claims should be broadly construed."). The FCA "reaches beyond 'claims' which might be legally enforced to all fraudulent attempts to cause the Government to pay out sums of money." *Neifert-White* at 233; *see also Cook County v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003) ("Congress wrote [the FCA] expansively, meaning 'to reach all types of fraud, without qualification, that might result in financial loss to the Government.'")(citation omitted). "'[T]he [FCA] is violated not only by a person who makes a false statement or a false record, . . . but also by one who engages in a *fraudulent course of conduct* that causes the government' to lose money by honoring a false claim." *Raymond & Whitecomb Co.*, 53 F. Supp. 2d at 445 (emphasis added; citation omitted).

Under a "fraudulent course of conduct" theory, FCA liability reaches claims submitted to the United States when there was fraud underlying a contract, benefit or status that resulted in the presentment of a claim for payment. *See Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 788 (4th Cir. 1999). For example, with proof of bid-rigging or price collusion, courts

have had no difficulty finding that all the claims flowing from the resulting contract, although "truthful" on their face, are fraudulent and actionable under the FCA. *Id.* at 788-89; *see also Marcus*, 317 U.S. at 543-44; *United States ex rel. Hagood v. Sonoma County Water Agency*, 929 F.2d 1416, 1420-21 (9th Cir. 1991); *Murray & Sorenson, Inc. v. United States*, 207 F.2d 119, 123-24 (1st Cir. 1953); *United States v. CFW Construction Co.*, 649 F. Supp. 616, 618 (D.S.C. 1986), *appeal dismissed on other grounds*, 819 F.2d 1139 (4th Cir. 1987). The fraudulent course of conduct theory has been accepted in others contexts as well. This Court, in *United States ex rel. Franklin v. Parke-Davis*, 2003 WL 22048255 (D. Mass. 2003), found that FCA liability could lie when a relator alleged that the defendant drug company engaged in a fraudulent course of conduct through its misleading promotion of off-label uses of its drug that led to the submission of claims to the United States that were ineligible for payment under the Medicaid program. *See also, Island Park*, 888 F. Supp. at 440 (holding that defendant engaged in a fraudulent course of conduct by intentionally subverting the purposes of the affirmative fair market housing plan, causing the innocent mortgagees to submit fraudulent claims to the United States Department of Housing and Urban Development).

In this case, the United States has sufficiently alleged that Abbott engaged in a fraudulent course of conduct in that Abbott (1) reported inflated prices to price reporting compendia relied upon by Medicare and Medicaid to set reimbursement, (2) supplied those inflated prices to create artificially large spreads between Medicare and Medicaid reimbursement and the purchase price of Abbott's drugs, (3) marketed the spreads to customers as an inducement to purchase Abbott's drugs, and (4) withheld information and/or purposely provided misleading information that was critical to government decisions regarding amounts to pay on claims for Abbott's products.

Complaint *passim*. This conduct is analogous to that in *In re Lupron Marketing and Sales Practices Litigation*, where the Court observed, "[The TAP defendants] ... trumpeted a lie by publishing the inflated AWPs, knowing (and intending) them to be used as instruments of fraud." 295 F. Supp. 2d 148, 167-68 (D. Mass. 2003) (finding elements of misrepresentation satisfied).

In addition to Abbott's claims being false due to its fraudulent course of conduct, the United States also contends – as discussed *infra* in Section I(A)(4) – that the claims at issue in this matter are false because they arose out of violations of the AKS. *See, e.g. Thompson*, 125 F.3d 899 (violation of AKS can give rise to FCA liability); *Pogue*, 238 F. Supp. 2d 258(same); *Kneepkins*, 115 F. Supp. 2d at 43. That recognized theory of liability also gives rise to 31 U.S.C. § 3729(a)(1) liability regardless of whether the claims are "false on their face."

Legislative history and abundant case law make clear that the FCA must be read expansively. The United States submits that this Court should reject Abbott's attempt to unduly narrow the types of fraud actionable and theories of liability available under the FCA (as set forth in the First and Second Causes of Action in the Complaint).

b. Abbott Reported False Prices For Its Products.

Abbott argues that the United States has not adequately alleged falsity because the United States does not explain (1) why the prices Abbott reported for the drugs at issue are "too high" and (2) what the reported prices were "supposed to be." Memorandum of Law at 10-11.

The United States need not plead the one price that Abbott should have reported for each drug for each year to adequately plead falsity. The United States has sufficiently pled that the prices Abbott knowingly reported were false and fraudulent. The prices Abbott reported were false and fraudulent because Abbott was not selling the drugs for prices that were remotely close

to the prices that it reported to the compendia relied upon by the government and other third party drug payors. Abbott set its reported prices to create and market illegal inducements in the form of huge spreads between the Medicare and Medicaid reimbursement amounts and the market prices available to its customers. Abbott used these illegal inducements, funded by the public fisc, for private gain at the expense of the Medicare and Medicaid programs and taxpayers.

In Exhibit 1 to the Complaint, the United States provides a comparison of AWPs that were calculated using prices reported by Abbott (*see* Complaint ¶¶ 59-61) and the prices available to the Relator, Ven-A-Care of the Florida Keys, Inc. ("Ven-A-Care" or "Relator"), a small pharmacy in Key West, Florida. The spreads range from 297% to 1,716%, with the majority being more than 1000%. *See Id*. In other words, the published AWPs for the drugs in the Complaint – which were determined by prices Abbott reported – were typically **10** or more times higher than the prices which Abbott was actually charging its customers for the drug. As Judge Stearns noted in *In re Lupron*: "There is a difference between a sticker price and a sucker price." 295 F. Supp. 2d at 168 n.19 (commenting on 300% spread on Lupron).[3] As in *In re Lupron*, the prices reported by Abbott similarly bore no relationship to the actual market prices for the drugs, were used to create large spreads, and caused the submission of false or fraudulent claims to the government. These inflated prices were therefore false and fraudulent.[4]

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[3] Abbott was a partner with Takeda Chemical Industries, Ltd. ("Takeda") in the venture (TAP Pharmaceuticals) that manufactured and marketed Lupron.

[4] Additionally, Abbott contends the United States could not possibly have wanted to reimburse at acquisition cost because (1) the fact that Medicare reimbursed at 95% of AWP recognizes there was some disparity between AWP and actual acquisition costs and (2) health care providers would not have participated in the Medicare and Medicaid programs unless they

The answer to Abbott's contention that there is no falsity because the Government has never said what Abbott should have reported is rather simple and obvious: the prices Abbott should have been reporting are the market-based prices Abbott started reporting in January 2001. Complaint at ¶¶ 83-85. For example, Abbott's reported prices resulted in an AWP for its 1 Gram dose of Vancomycin of $76.42 per unit in early 2001; after Abbott started reporting prices closer to what it actually charged on the market, the AWP dropped to $6.06 a unit by 2002. Complaint at ¶ 84. Abbott could have and should have reported those prices all along. Instead, Abbott apparently made a business decision to submit fraudulent pricing information until the time that TAP Pharmaceuticals was being investigated for similar conduct. Abbott's decision to finally report market-based prices beginning in January 2001 is a reflection of the falsity of the inflated prices it reported prior to then.

Ultimately, the issue of what price Abbott should have reported is really one of damages rather than liability and will be informed by all the pricing and sales information about the drugs at issue that Abbott will have to produce in discovery.

c. The United States' Use Of AWP To Determine The Estimated Acquisition Cost For Abbott's Drugs Does Not Estop The United States from Pursuing Abbott Under the FCA for Abbott's False Price Reporting.

Abbott argues that the United States' allegations that its AWPs were false just "cannot be right" and contends that the United States must be estopped from arguing that AWP should have

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received the massive Abbott spreads in part to offset losses incurred on other items or services. Memorandum of Law at 12-13. Abbott's arguments about "cross-subsidization" should be rejected. There is a difference between cross-subsidization and creating illegal remuneration to induce customers to buy Abbott drugs. As Judge Stearns in this District noted, "The suggestion that Congress would deliberately condone a bribery scheme using public funds to enrich drug manufacturers and doctors is, to say the least, unusual." *In re Lupron*, 295 F. Supp. 2d at 163.

been a proxy for "actual acquisition cost(s)." Memorandum of Law at 11-13. Abbott's argument rests on its contention that various government reports note that AWP may not reflect "an actual acquisition cost." As set forth in the Complaint, both the Medicaid and Medicare systems generally sought to reimburse providers at the *estimated* acquisition cost of Abbott's drugs, not "an" or "one" particular acquisition cost. *See* Complaint at ¶¶ 39-41, 46-48.

Regardless, courts have been extremely hesitant to apply the doctrine of equitable estoppel against the government, and have only considered applying the doctrine when there was evidence of some sort of affirmative misconduct by government agents that was reasonably relied upon by a party.[5] *See Office of Personnel Management v. Richmond*, 496 U.S. 414, 421 (1990) (noting that some dicta in Supreme Court decisions "mention the *possibility* ... that some type of 'affirmative misconduct' might give rise to estoppel against the government.") (emphasis added); *Frillz, Inc. v. Lader*, 104 F.3d 515, 518 (1st Cir. 1997) ("A party seeking to invoke equitable estoppel against the federal government at a minimum 'must have reasonably relied on some

[5] To the extent that Abbott relies on the government reports to support defenses of laches, estoppel or waiver, such arguments should be rejected. It is well established that "[m]en must turn square corners when they deal with the government." *Heckler v. Community Health Services*, 467 U.S. 51, 63 (1984) (citation omitted) (rejecting estoppel argument in Medicare overpayment case). Openness and honesty are required if the Medicare system is "not to be turned into a cat and mouse game in which clever providers could, with impunity, practice fraud on the government." *United States v. Calhoon,* 97 F.3d 518, 529 (11th Cir. 1996) (affirming conviction for submitting false cost reports to Medicare). "Available time and resources do not permit audit of more than a fraction of the [claims] filed. [Defendant's] filing of reports ... while concealing or disguising their true nature was a deliberate gamble on the odds that they would not be questioned." *Id.* Because "'those who deal with the Government are expected to know the law,'" they "'may not rely on the conduct of Government agents contrary to law'" in order to escape liability under the FCA. *Hagood*, 929 F.2d at 1422 (citing *Heckler*, 467 U.S. at 63). Accordingly, such defenses are inapplicable here.

'affirmative misconduct' attributable to the sovereign.'"), *quoting*, *United States v. Ven-Fuel, Inc.*, 758 F.2d 741, 761 (1st Cir. 1985).

Abbott cannot identify any affirmative government misconduct upon which it reasonably relied. The government reports Abbott cites reflect general concerns and do not constitute misconduct by any government agent in this case encouraging Abbott to report false prices and create financial windfall profits for its customers. Moreover, Abbott points to no document showing that it sought advice or guidance before it engaged in the practice of reporting inflated prices. In fact, the only "guidance" Abbott received from the government about the propriety of reporting inflated prices came in the form of the government's investigation into TAP Pharmaceutical's similar price manipulation and marketing the spread, an investigation that resulted in a guilty plea and global settlement by TAP Pharmaceuticals in 2001.[6] Complaint at ¶ 83.

Abbott also contends that the government should be estopped in this case because Abbott reported Average Manufacturer Prices ("AMP") to the Medicaid drug rebate program. Abbott claims that this information should have allowed the government to discern something approximating Abbott's actual sales prices notwithstanding its false price reporting. The reporting of AMP to the Medicaid drug rebate program was not used to set reimbursement rates for Abbott's drugs and is irrelevant to this case. In addition, it remains to be seen whether Abbott's AMPs truly represented estimated acquisition cost. But, most importantly, Abbott knew that state Medicaid programs and Medicare relied on Abbott's published AWPs to set

[6] TAP Pharmaceuticals paid $875 million to resolve its criminal responsibility and civil liability under the FCA and the AKS. During the course of that investigation, Abbott began reporting prices the more closely reflected actual sales prices. Complaint at ¶ 83.

reimbursements for the drugs at issue. *See Id*. at ¶¶ 63, 66. Abbott manipulated the published AWPs on its drugs because it knew (1) the published AWPs had a direct impact on government reimbursement systems in place and (2) inflated Government reimbursement could be an effective marketing tool. Abbott could have just reported one number both (1) as its AMP to the Medicaid drug rebate program and (2) to the pricing compendia relied upon by Medicare and Medicaid to set reimbursement levels. Instead, Abbott reported inflated prices to the price reporting compendia because doing so advanced Abbott's overall fraudulent scheme.

The United States was not required to "reverse engineer" Abbott's AMPs, compare them to Abbott's false AWPs and then take corrective action, and the absence of such efforts does not render the claims affected by Abbott's false price reporting any more true. Furthermore, as this Court has observed, "the ability to make a mathematical calculation" to detect inaccuracies in prices reported by a pharmaceutical company does not preclude a finding of liability. *The Commonwealth of Massachusetts v. Mylan Laboratories, et al.*, 357 F. Supp. 2d 314, 323 (D. Mass. 2005) (discussing common law claims).

d. There Is Nothing Ambiguous About Abbott's False Price Reporting.

Abbott argues that it cannot be liable because the pricing terms identified in the Complaint are ambiguous. Memorandum of Law at 13. Citing *U.S. v. Napco, Inc.*, 835 F. Supp. 493 (D. Minn. 1993), Abbott argues that the United States cannot now apply an "interpretive afterthought" to undo the harm to the public fisc caused by Abbott's (and other manufacturers') false and fraudulent price reporting. However, *Napco* is inapposite. *Napco* does not stand for the proposition that the Government cannot state its view on what was or was not a true AWP; it

simply addresses whether deference should be given to certain agency interpretive regulations under *Chevron v. National Reources Defense Council*, 467 U.S. 837 (1984).

Abbott argues that its interpretation of AWP – *i.e.*, AWP was whatever Abbott wanted it to be – was a reasonable interpretation of a supposedly ambiguous term. This argument does not go to the falsity of the claims at issue; at most, it goes to Abbott's scienter.[7] *See United States ex rel. Oliver v. Parsons Co.*, 195 F.3d 457, 463 (9th Cir. 1999) ("[W]hile the reasonableness of Parsons' interpretation of the applicable accounting standards may be relevant to whether it knowingly submitted a false claim, the question of "falsity" itself is determined by whether Parsons' representations were accurate in light of applicable law.").

As set forth in the United States' September 15, 2006 Amicus Curiae Brief on the meaning of AWP, the legislative and regulatory history of Medicare drug reimbursement demonstrates that AWP was contemplated and used by both Congress and the Secretary to describe estimates of prices available in the marketplace, and, accordingly, the Court should apply the plain meaning rule to the term "Average Wholesale Price." United States' September 15, 2006 Amicus Curiae Brief *passim*. Thus, to find falsity in this case, a Court or jury does not have to engage in a complex interpretive exercise with respect to the meaning of AWP or any other pricing term. To find falsity in this case, the Court need only examine the relationship between the prices Abbott reported and the prices at which Abbott actually sold the drugs listed in the Complaint.

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[7] The case cited by Abbott for its ambiguity argument, *United States ex rel. Cox v. Iowa Health Sys.*, 29 F. Supp. 2d 1022, 1026 (S.D. Iowa 1998), is inapposite. That case concerned whether an air ambulance operator could bill for "nautical" or "statute" miles when the governing law was silent. This case is about the falsity of Abbott's reporting a $65 price for Vancomycin when it actually sold the drug for closer to $5, not the use of one pricing term versus another.

Ironically, the subtext to Abbott's ambiguity argument is that the term "AWP" is meaningless because manufacturers, such at itself, have submitted inflated and perhaps false AWPs in the past; if everyone reported a price approximating real average wholesale prices, presumably Abbott would not be arguing the term was ambiguous – the term would mean what it says. Moreover, Abbott never once sought guidance on what prices it should submit. Instead, Abbott submitted false prices and marketed illegal inducements, and now Abbott seeks to sanitize its conduct behind *ex post facto* claims of statutory or regulatory ambiguity.

Abbott also argues that industry practice should determine whether or not Abbott violated the FCA by submitting inflated AWPs. Memorandum of Law at 14. While it may have been Abbott's practice to submit false information for the drugs in the Complaint, it certainly has not been established that it was an appropriate "industry custom" to submit inflated pricing information that was often 10 times actual selling prices so as to have a more marketable spread. Even if some drug manufacturers submitted similarly inflated pricing information, Abbott can point to no authority that the United States affirmatively blessed an industry custom of wildly

inflating AWPs when it chose to use AWP as a reimbursement benchmark.[8] A fraudulent practice becomes no more legitimate simply because others are engaged in similar misconduct.

2. The Complaint Sufficiently Alleges That Abbott Caused False Claims to Be Presented.

Abbott argues that the United States failed to allege adequately that Abbott caused the presentment of claims to the Government. Abbott's basic argument is that knowledge of the submission of a claim that may be false does not equate to "causing" the submission of a false claim. Memorandum of Law at 19-20. Abbott's argument fails for two reasons. *First*, the United States does not premise its allegations regarding causation on simply Abbott's knowledge of the submission of claims. *Second*, the Complaint amply alleges that Abbott (1) manipulated Medicare and Medicaid reimbursement levels for its drugs and (2) created unlawful inducements for its purchasers, thereby causing the submission of false claims for certain Abbott drugs by those purchasers to Medicare and Medicaid.

By its plain terms, the FCA is directed not merely at those who submit false claims but also at those who "cause" false claims to be submitted. 31 U.S.C. § 3729(a)(1), (2). The Act contains no requirement that there has to be an affirmative act of instruction or direction in order

[8] In support of this argument, Abbott quotes one case, *United States ex rel. Gathings v. Bruno's, Inc.*, 54 F. Supp. 2d 1252 (N.D. Ala. 1999), out of context. The *Bruno* case involved an interpretation of Alabama Medicaid drug reimbursement regulations that called for the reimbursement to be at the lower of (1) estimated acquisition cost plus a dispensing fee, (2) a federal upper limit plus a dispensing fee, (3) a state-imposed maximum allowable cost or (4) the usual and customary charge to the general public for the drug. *Id*. at 1256 The issue in that case was whether the "usual and customary charge to the general public" meant a prevailing retail price or covered the prices negotiated by large state insurers. *Id.* at 1257, 1260. The court decided to apply a plain meaning interpretation of the term "charge to the general public" in the absence of a federal or state statute or regulation. *Id*. at 1260. *Gathings* does not stand for the proposition that absent an additional regulation or statutory definition of AWP, Abbott could legally report false prices as others in the industry may have.

for liability to exist for "causing" the submission of a false or fraudulent claim. Indeed, the prototypical situation involving the submission of a false claim – when a subcontractor submits a false invoice to a prime contractor which, in turn, submits the invoice to the United States rarely involves a subcontractor affirmatively instructing or directing the prime contractor to submit a false claim. *See, e.g., United States v. Bornstein*, 423 U.S. 303, 309 (1976); *Hess*, 317 U.S. at 543-45.

As this Court explained in *Parke-Davis II*, the causation requirement under the FCA follows general tort principles. *Parke-Davis*, 2003 WL 22048255 at *4-6. The FCA does not provide a special definition for causation: "[t]he first question is whether there was in fact some causal relationship between the conduct and the outcome. The *Restatement* expresses this test as whether the defendant's conduct was a 'substantial factor in producing the harm.' The second question is whether the circumstances and causal relationship are such that the law will impose liability on the defendant. Sometimes this is expressed as a foreseeability test." *Id.* at *11-12 (citations omitted). *See also United States v. President & Fellows of Harvard University*, 323 F. Supp.2d 187 (D. Mass. 2004) ("Most courts agree that the FCA covers 'indirect mulcting of the government.'"), *quoting*, *United States v. Lagerbusch*, 361 F.2d 449 (3rd Cir. 1996). *See also United States ex rel. Schmidt v. Zimmer, Inc.*, 386 F.3d 235, 244 (3rd Cir. 2004) (applying ordinary causation principles under FCA); *United States ex rel. Cantekin v. University of Pittsburgh*, 192 F.3d 402, 411-17 (3rd Cir. 1999) (finding liability for causing false claims to be submitted as long as the resulting submission of the ineligible charge by the third party was "reasonably foreseeable."). Thus, all that is required is a showing that a defendant's conduct was a substantial factor in producing the harm, and that such harm was foreseeable. *Parke-Davis*,

2003 WL 22048255 at *4. As is clear from *Parke-Davis*, a determination of causation is a fact-based, evidentiary inquiry that is not proper for adjudication in a Rule 12(b)(6) motion. *Id*. at *5.

As alleged in the Complaint, Abbott reported false, fraudulent and inflated drug prices for certain drugs to several price reporting compendia that the Medicare and Medicaid programs relied upon to set reimbursement rates for Abbott's customers. Abbott knew that the Medicare and Medicaid programs relied on Abbott's reported prices to those compendia to set reimbursement rates for claims submitted for Abbott's drugs. *See* Complaint at ¶ 66 (Abbott's Manager for Reimbursement noted in an April 26, 1995 memorandum, "[h]aving a published [DP] that is high allows a provider to bill at that list price."). Thus, Abbott did not merely know about claims being submitted using Abbott's pricing; its conduct of reporting fraudulent prices commenced a process that led to the government reimbursing claims for Abbott's drugs at inflated rates, resulting in substantial profits to its customers. Indeed, the Complaint alleges that Abbott created this "spread" precisely to induce purchasers to buy Abbott products, purchasers who would realize those profits by submitting claims to Medicare and Medicaid. Thus, the United States has sufficiently alleged that it was foreseeable that Abbott's conduct "would ineluctably result in false . . . claims." *Parke-Davis*, 2003 WL 22048255 at *5; *see also In re Lupron*, 295 F. Supp. 2d at 175 ("[I]t was the defendants who instigated both the culpable and the innocent intermediaries to commit acts that were not only foreseeable but intended.").

The First Circuit addressed a defendant's required role in causing the presentment of false claims in *Rivera*, where defendants siphoned money from a hospital through a scheme involving selling goods at inflated prices by a company controlled by defendants. After the fraud caused the hospital to default to Merrill Lynch on its mortgage, Merrill Lynch filed for insurance

benefits from the United States Department of Housing and Urban Development ("HUD"). *Rivera*, 55 F.3d. at 706. The Court noted that the case was "complicated" by the fact that the initial fraud was perpetrated against a private lender. Nevertheless, the Court found that the application to HUD could form the basis for FCA liability because the fraud resulted in the hospital's default, which then resulted in Merrill Lynch's claims to HUD. *Id.* at 706-07. As the Court explained, "case law allows the United States, in such circumstances, to sue defendants under the FCA for having 'caused' the filing of a 'false' claim against the government." *Id.* at 707. Plainly, the defendants there had not specifically *caused* Merrill Lynch to file an insurance claim, but they were the cause of that claim being rendered ineligible by fraud.[9]

Abbott relies heavily on one case, *United States ex rel. Kinney v. Hennepin County Med. Ctr.*, 2001 WL 964011 (D. Minn. 2001). However, this Court distinguished *Kinney* in *Parke-Davis II*, noting the difference where evidence showed that defendant's actions were "not irrelevant, but, rather, played a key role in setting in motion a chain of events that led to false claims." *Parke-Davis II*, 2003 WL 22048255 at *6 (expressly rejecting defendant's argument

[9] Numerous other courts have upheld FCA allegations based on broad interpretations of the causation element. *See, e.g.*, *Zimmer*, 386 F.3d at 243-44 (although defendant had not reviewed, approved or received copies of [hospital's] cost reports or participated in their filing, defendant's creation and pursuit of marketing scheme that, if successful, would lead to filing of false claims satisfied causation); *Scolnick v. United States*, 331 F.2d 598, 599 (1st Cir. 1964) (liability for accepting government payment known to have been made in error); *United States ex rel. Drescher v. Highmark, Inc.*, 305 F. Supp. 2d 451, 457-58 (E.D.Pa. 2004) (sustaining FCA claims where government alleged that defendant's knowing dereliction of its obligation to pay claims or to pay as primary payer resulted in claims being presented to Medicare); *Pogue*, 238 F. Supp. 2d at 267 (rejecting defendant's argument that it had not filed or caused claims to be filed); *Island Park*, 888 F. Supp. at 439 (FCA reaches all fraudulent attempts to cause the government to pay sums of money); *United States v. Teeven*, 862 F. Supp. 1200, 1223 (D. Del. 1992) (defendants, whose policy of withholding refunds due to students resulted in inflated default claims to government, were liable under FCA because they "knowingly assisted in causing the government to pay claims which were grounded in fraud").

that it could not be held liable under FCA because it exerted no control over and did not directly influence the filing of a false claim).[10] As this Court recognized, *Kinney* involved information submitted on a claim form that was either (1) not attributable to the defendant or (2) submitted and handled in the same fashion regardless of any information that the defendant had provided.[11] *Kinney*, 2001 WL 964011 at *10. Notably, the *Kinney* case was decided on a motion for summary judgment, not a motion to dismiss. Here, of course, Abbott's information was an integral and necessary component of the government's reimbursement to the health care providers for Abbott's drugs. The other cited authorities in Abbott's brief are either of no consequence or support the United States' position.[12]

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[10] Nor is it of any significance whether the parties submitting the individual claim forms (here, health care providers) knew that the claims would be infected with falsity. *E.g, Zimmer,* 386 F.3d at 243-44 (Supreme Court opinions' in *Hess* and *Bornstein* demonstrate that the outcome of FCA claims against a party that caused another entity to submit false claims "did not turn on whether the actual presenters were 'duped' or participated in the fraudulent scheme").

[11] Plaintiff in *Kinney* had sued HFA, a corporation that provided emergency room physician staffing for a hospital, claiming that HFA physicians had falsely checked a "medical necessity" box on hospital forms pertaining to ambulance transport. Medical necessity was required for Medicare payment. The court granted summary judgment to HFA because HFA played no role in the hospital submission of Medicare claims, did not provide physician certifications for use with Medicare claims and did not delegate authority for anyone to submit Medicare claims. *Id.* at *32. Even more significantly, the information submitted by the hospital to Medicare and used to determine eligibility for Medicare payment were codes that the defendants did not select and that were not triggered by the medical necessity check-off by the defendants. Indeed, evidence demonstrated that the codes necessary for Medicare reimbursement were filed on the hospital's Medicare claims regardless whether HFA physicians had checked the box or not on the internal forms. *Id.* at *34-35.

[12] For example, the *Shaver* case actually stands for the same proposition stated in *Parke Davis* that the submission of the claim must be foreseeable. *United States ex rel. Shaver v. Lucas Western Corp.* 237 F.3d 932, 933-34 (8th Cir. 2001) (finding that defendant's refusal to pay relator's medical bills from disability claim did not "cause" the submission of a claim for such medical bills to Medicare). Likewise, in the *Harvard* case, the court found that "some degree of participation in the *claims process* is required." *Harvard*, 323 F. Supp. 2d at 186-87 (emphasis

3. The "Government Knowledge" Abbott References Does Not Negate Abbott's Liability Under The FCA.

Abbott spends a significant portion of its brief giving its interpretation of various reports issued by the Department of Health and Human Services ("HHS") and its predecessor agency, Congress and other government agencies on the use of AWP for drug reimbursement. Abbott seeks to use these reports as a shield against liability for the conduct set forth in the Complaint. These reports provide absolutely no basis for dismissing this action.

"Government knowledge" is not a defense to an FCA claim. The FCA is violated by knowingly presenting, or by knowingly causing the presentation, of a claim that is either false or fraudulent. The requisite scienter is "the knowing presentation [or causing the presentation] of what is known to be false." *Hagood*, 929 F.2d at 1421. "That the relevant government officials know of the falsity is not in itself a defense." *Id.* Indeed, courts have held that "even a contractor who tells a government contracting officer that a claim is false still violates the statute when the false claim is submitted." *United States ex rel. Mayman v. Martin Marietta Corp.*, 894 F. Supp. 218, 223 (D. Md. 1995). As a result, no case has held that government knowledge automatically or invariably absolves a defendant of liability. *See, e.g., United States ex rel. Kreindler & Kreindler v. United Technologies Corp.*, 985 F.2d 1148, 1156 (2nd Cir. 1993).

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added). The court distinguished claims against one individual who took no actions in connection with claims submissions and who did not approve the expenses at issue, but upheld claims against a second individual whose participation in approving invoices played a role in the forms ultimately submitted for payment. *Id*. at 188. The second individual's failure to file or review any of the forms deemed to constitute claims was not dispositive because his actions "were tied to the claims process." *Id*. The prices Abbott reported were certainly tied to the claims process; their reports of inflated prices affected reimbursement for those claims. *See* Complaint ¶¶ 31-50.

At most, evidence about government knowledge is only relevant under the FCA to the extent that it serves to negate a defendant's scienter. *See United States ex rel. Becker v. Westinghouse Savannah River Co.,* 305 F.3d 284, 289 (4th Cir.2002); *Kreindler*, 985 F.2d at 1157; *Shaw v. AAA Eng'g & Drafting, Inc.*, 213 F.3d 519, 534 (10th Cir. 2000).

To show that its knowledge was negated, the defendant must offer credible evidence of a meeting of the minds between a defendant and the government such that the defendant reasonably believed that its representations were accurate and its conduct was permissible. To show such, courts have required that the defendant (1) prove that it identified a problem with performance under a contract, (2) fully disclosed the problem to the government, and (3) completely cooperated with the government to resolve the problem. *See, e.g., United States ex rel. Costner v. URS Consultants, et al.*, 317 F.3d 883, 888 (8th Cir. 2003) (defendants' "openness with the EPA about [problems in the cleanup of a hazardous site] and their close working relationship in solving the problems negated the required scienter" under the FCA); *Shaw*, 213 F.3d at 534 (defendant's knowledge was not negated where defendant was not forthcoming about its conduct and "repeatedly evaded government employees' questions" about its failure to recover silver from photo lab chemicals); *United States ex rel. Butler v. Hughes Helicopters, Inc.*, 71 F.3d 321, 327-29 (9th Cir. 1995) (defendant "completely cooperated and shared all information" during the testing of Apache helicopters); *Wang ex rel. United States v. FMC Corp.*, 975 F.2d 1412, 1421 (9th Cir. 1992) (defendant disclosed a deficiency with a howitzer to the Army and had a dialogue about how to fix it). Abbott does not cite one case where a defendant has ever prevailed on a motion to dismiss an FCA case with a government knowledge

argument. Moreover, even at the summary judgment stage, courts set a high bar for defendants, and the argument has rarely succeeded.

There are good reasons why, in the majority of cases, evidence of government knowledge does not entitle the defendant to dismissal of the claims against it. As noted, the defendant still may know that its claim is false or fraudulent even if the government also is aware of or suspects the fraud. Further, the government may acquire knowledge of the fraud or falsehood too late in the process to risk disrupting important government programs or objectives. *See Island Park*, 888 F. Supp. at 442 (noting that government continued to pay fraudulent claims "only because it had already become contractually bound to make those payments as a result of the defendant's fraudulent course of conduct"). A decision not to pay a claim that the government knows to be false could effectively stop the delivery of goods and services that are essential to the United States or could result in damage to third parties, such as Medicare beneficiaries. *See United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 917 (4th Cir. 2003) (identifying "instances in which a government entity might choose to continue funding the contract despite earlier wrongdoing by the contractor").

Abbott's motion to dismiss contains not a scintilla of evidence to show that it made a full disclosure, had an open dialogue, or completely cooperated with the government regarding the company's reporting of inflated drug prices. In fact, as the United States' Complaint alleges, Abbott did just the opposite. Complaint at ¶¶ 38,66. Abbott concealed when it could have disclosed; it obfuscated when it could have cooperated. Indeed, Abbott has failed to provide a single company document or excerpt of employee testimony to support a claim that it reasonably

believed that its conduct was permissible because of communications that it had with the government.

The United States' lawsuit is about *Abbott's* false price reporting for the *Abbott* drugs identified in ¶¶ 31 and 35 of the Complaint, *Abbott's* marketing of the government-funded spread on its drugs to its customers, and *Abbott's* impact on the Medicare and Medicaid programs through this conduct. The United States did not purposefully invite Abbott to report inflated prices (often at 10 times actual sales prices) for its drugs and willingly pay spread profits to Abbott's customers. Consequently, there is little credibility to Abbott's claim that it reasonably believed that any particular government report gave it *carte blanche* to manipulate its reported prices. As it has before, this Court should reject Abbott's attempt to divert the focus away from its own fraudulent conduct. *In re Pharmaceutical Industry AWP Litigation*, 263 F. Supp. 2d 172, 187 (D. Mass. 2003)("the fact that Congress has failed to disturb the widespread practice on the part of pharmaceutical companies of grossly overstating their AWPs cannot be read as a clear and manifest intention to grant immunity from state regulation of such fraudulent practices."); *In re Lupron*, 295 F. Supp.2d at 163 (rejecting notion that "Congress deliberately invited the very fraud of which defendants are accused.").

For the reports Abbott appends to its motion to have evidentiary value as to Abbott's scienter under the FCA, Abbott must show how a report bore on its scienter. At most, the government reports reflect concerns about the use of published prices to set drug reimbursement. The existence of these concerns, however, does not legitimate Abbott's actual abuse of the reimbursement systems. Nor do the policy considerations for using an AWP-based reimbursement scheme Abbott sets forth in its brief in any way justify Abbott's false price

reporting and fraudulent conduct. Thus, the recognition by federal regulators that providers could acquire certain drugs at lower prices than the reported AWPs does not mean, as Abbott contends, that the regulators knew that Abbott (1) reported prices for *its* drugs that were inflated for the purpose of creating artificially large spreads and (2) reported prices that *no one* paid.

In prior AWP matters in this District, Abbott and other defendants have offered all the same congressional reports, testimony, and agency reports for a variety of purposes, and the courts properly ascribed little to no weight to them. Judge Stearns observed that "[t]he recognition on the part of government regulators of inefficiencies in the administration of Medicare does not, as defendants contend, amount to condonation of fraudulent conduct." *In re Lupron*, 295 F. Supp. 2d at 168 n.19.

Indeed, as this Court has noted, the harm suffered by the United States in this matter stems not from the AWP system as Congress established it, but from Abbott's abuse of that system through its fraudulent price reporting. *See In re Pharmaceutical Industry AWP Litigation*, 263 F. Supp. 2d at 192 (rejecting defendants' argument under the government action doctrine, stating "[t]his doctrine is inapplicable to the case at bar because plaintiffs do not claim that the harm they suffer stems from the AWP system as Congress has established it, but rather from the defendants' fraudulent statements about their average wholesale prices.").

These decisions suggest that what matters is the proof and evidence as to each defendant, and that generalized arguments about "government knowledge" are insufficient to defeat the claims set forth in the United States' Complaint.

4. The United States' Complaint Sufficiently Alleges that Abbott Violated the Anti-Kickback Statute as a Predicate for a Violation of the FCA.

The Anti-kickback Statute ("AKS") prohibits the knowing and willful offering of any remuneration to induce referrals of services for which payment may be made under a federal health care program. 42 U.S.C. § 1320a-7b(b). When a person violates the AKS and obtains referrals or other business as a result, the claims relating to such referred items or services are not eligible for reimbursement because compliance with the AKS is a condition of payment. *United States ex rel. McNutt v. Haleyville Medical Supplies, Inc. et al.*, 423 F.3d 1256, 159-160 (11th Cir. 2005); *see generally Schmitt*, 386 F.3d at 245 (violation of AKS can give rise to FCA liability); *Thompson*, 125 F.3d at 902 (same); *Pogue*, 238 F. Supp. 2d at 266 (same). When an entity knowingly submits or causes the submission of claims resulting from an illegal remunerative arrangement, it has presented or caused the submission of a false or fraudulent claim in violation of the FCA. *Id.* To hold otherwise would "put the government in the position of funding illegal kickbacks after the fact." *United States ex rel. Bidani v. Lewis,* 264 F. Supp. 2d 612, 615 (N.D. Ill. 2003).

a. The Anti-Kickback Statute Prohibits Offering Illegal Remuneration to a Third Party.

Abbott argues that arranging for the United States to fund illegal payments to Abbott's customers is not actionable because government reimbursement cannot qualify as a "kickback" under the AKS. Abbott's argument reads the United States' Complaint too narrowly and contradicts the express language of the statute.

The United States has alleged that Abbott offered illegal remuneration to its customers in violation of the AKS. The United States did not limit itself to alleging only payments in the form

of "kickbacks" under the statute, but instead described conduct in violation of and quoted from the entire section of the statute dealing with the broader concept of "remuneration." The statute is quite clear that both "direct" or "indirect" remuneration of any kind to health care providers and suppliers is prohibited. In pertinent part, the AKS, codified at 42 U.S.C. § 1320a-7b(b) (as amended), reads:

> (b) Illegal remuneration
>
> * * *
>
> (2) whoever knowingly and willfully offers or pays *any remuneration* (including any kickback, bribe, or rebate) *directly or indirectly, overtly or covertly, in cash or in kind* to any person to induce such person --
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b) (emphasis added). As is clear from the plain language of the statute, a kickback is merely one of several types of illegal remuneration that can give rise to AKS liability. *See United States v. Greber*, 760 F.2d 68, 71 (3rd Cir. 1985) ("That a particular payment was a remuneration (which implies that a service was rendered) rather than a kickback, does not foreclose the possibility that a violation [of the AKS] nevertheless could exist."). The statute makes clear that offering indirect remuneration that induces a provider to purchase Abbott drugs

for which payment may be made under Medicare and Medicaid – which is what Abbott did here by causing inflated government reimbursement for its drugs as alleged in the Complaint – is illegal. *Id*. at § 1320a-7b(b)(2); *see also Greber*, 760 F.2d at 72 (remuneration under AKS was intended to be expansive and encompass any payments that induce providers to purchase certain goods and services that are later billed to federal programs); *cf. United States v. Bay State Ambulance and Hospital Rental Service, Inc.*, 874 F.2d 20, 29 (1st Cir. 1989)("Giving a person the opportunity to earn money may well be an inducement to that person to channel potential Medicare payments towards a particular recipient.").

In *United States v. Mittal*, 1999 WL 461293 (S.D.N.Y. July 7, 1999), the defendant argued that because he was charged under the statute with accepting "kickbacks," he could not be convicted because the "kickbacks" consisted of "sting" money supplied by federal agents. The district court found that defendant was charged more broadly with receiving remuneration in violation of the statute. *Id*. at *8. The court held that the violation of the statute was accomplished when the defendant allegedly accepted the money in return for unlawful patient referrals. *Id*. at *7. Thus, the source of the funds used to pay the illegal remuneration is irrelevant, and federal funds clearly may serve as illegal remuneration.[13] *See, e.g., United States v. Killough*, 848 F.2d 1523, 1525 (11th Cir. 1988) (kickbacks paid from federal funds in procurement fraud scheme gave rise to FCA liability).

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[13] Indeed, defendants typically – and unsuccessfully – take the opposite position that the AKS *requires* the government to show that Medicare funds were used to make the illegal payments. See *Bay State*, 874 F.2d at 35; *United States v. Ruttenberg*, 625 F.2d 173, 177 (7th Cir. 1980). In those cases, defendants generally argued that the government cannot show that the illegal relationship resulted in increased costs or losses to the Medicare program; here, by contrast, Abbott's false price reporting was intended to inflate Medicare and Medicaid drug reimbursement rates for its customers' benefit.

In this case, the violation of the AKS was complete when Abbott submitted false pricing information, and, through this purposeful manipulation, offered illegal remuneration to its customers in the form of inflated reimbursement from Medicare and Medicaid to induce potential customers to buy and bill the government for Abbott's drugs. In sum, the statute broadly prohibits illegal remuneration from any source; Abbott's reading of the AKS is inconsistent with the plain language of the statute and the case law broadly interpreting "remuneration" under the AKS.

b. Medicaid Claims Are Subject to AKS-Based FCA Liability

Abbott also argues that under the facts presented here, even if the AKS-based FCA theory of liability may apply to Medicare claims, it does not apply to the United States' Medicaid claims. Abbott contends that while health care providers are required to sign a federal form certifying to compliance with the AKS to obtain Medicare payments, no single federal certification is required for Medicaid payments from the states. Abbott argues: "It is that signed form that supports the theory that claims submitted in violation of the anti-kickback statute are implicitly 'false.'" Memorandum of Law at 23, *citing Pogue*, 238 F. Supp. 2d at 264 & n. 2.

The AKS, from its plain language, applies to illegal remuneration used to induce customers to buy and bill "Federal health care programs" for Abbott's drugs, not just Medicare. 42 U.S.C. § 1320a-7b. Moreover, the authority Abbott cites does not support this proposition. The foundation of the implied certification theory of liability is that the violation of the underlying statute, regulation or rule was material to the agency's decision to pay the claims that were presented. Courts have consistently held that a violation of the AKS is material to the

agency's decision to pay claims resulting from the prohibited relationship. *See e.g.*, *McNutt*, 423 F.3d at 1259-1260; *Pogue*, 238 F. Supp. 2d at 264-266; *Bidani*, 264 F. Supp. 2d at 615; *United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 20 F. Supp. 2d 1017, 1047 (S.D. Tex. 1998).

As Abbott observes, the *Pogue* court noted that the provider application and claim forms used in the Medicare program contain a certification of compliance with applicable laws and regulations, including the AKS. *Pogue* did not hold, however, that such a certification is *required* to show that compliance with an underlying statute or regulatory scheme is a condition of payment. Rather, that court concluded that the existence of such a certification removed any possible doubt that compliance was in fact material. *Pogue*, 238 F. Supp. 2d at 264. In an implied certification context, by its very name, liability is found even in the absence of an express certification. It is the act of knowingly presenting or causing to be presented a claim for payment when the claimant is not entitled to payment because of the underlying fraud that makes the claim false or fraudulent. "So long as the statement in question is knowingly false when made, it matters not whether it is a certification, assertion, statement or secret handshake; False Claims liability can attach." *Hendow*, 2006 WL 2530394 at *5. Therefore, the distinction that Abbott attempts to make between Medicare and Medicaid liability because of supposed differences in certifications made in the programs has no bearing on the validity of the legal theories presented by the United States nor the ultimate question of liability in this case.

c. Abbott's Conduct Caused the Submission of Claims in Violation of the FCA

Abbott concludes this portion of its brief by arguing that the United States must prove that it would not have paid the claim had it known of Abbott's illegal conduct, and that Abbott

can show that the United States "knew" that Abbott's AWPs did not reflect actual acquisition cost when the United States paid the claims. Abbott further argues that because Medicare reimburses based on a median AWP, Abbott's conduct was irrelevant to determining how much the government paid for Abbott's drugs.

Abbott misstates the appropriate standard under the FCA.[14] The United States need not allege, nor prove, that it "would not have paid claims submitted for the Abbott drugs at issue had it known of the allegedly 'inflated' AWP for the drug." Memorandum of Law at 24. Rather, the cases are clear that all that is required is that the defendant's fraudulent conduct had a natural tendency to influence or was capable or influencing agency action. *See Harrison*, 352 F.3d at 914. In other words, the Government need only allege that the defendant's misconduct could have – not would have – affected the decision to pay. *Id.* at 916-17 (finding that courts give effect to the FCA by holding a party liable if its conduct had a natural tendency to influence agency action, not whether such conduct actually influenced the government not to pay a particular claim). Here, the United States has sufficiently alleged not only that the false and fraudulent prices that Abbott reported had a tendency to influence agency action, but in fact were critical to the setting of government reimbursement rates for Abbott's drugs and to the government's determination to pay the claims. *See generally*, Complaint at ¶¶ 31-50.

With respect to Abbott's causation argument, if Abbott's false price was sufficiently high to increase the median set by the Medicare program, then Abbott clearly affected the amount of reimbursement provided by the Government, not just to Abbott's customers, but also to

[14] The United States addresses Abbott's arguments regarding "government knowledge" in Section I(A)(3), *supra*, of its brief and refers the Court to that discussion.

customers of Abbott's competitors who bought competing drugs. Complaint at ¶¶ 46-50 (Medicare used manufacturer AWP pricing information to set median AWP and reimbursement amounts). Even if Abbott's price did not increase the Medicare median reimbursement during a particular time period, Abbott remains liable for submitting false information which Abbott knew would be used (1) by the Medicare program to calculate reimbursement (2) for the creation of illegal remuneration and kickbacks for Abbott's customers. The United States' Complaint has sufficiently alleged that every time Abbott submitted false pricing information, Abbott effectively gambled as to whether its falsity would affect the median. The extent to which Abbott's false information impacted actual reimbursement is a damages issue, and does not go to the sufficiency of the Complaint nor Abbott's liability.

B. The United States Properly Alleged False Statements by Abbott in Support of Its Common Law Fraud Claim

As Abbott suggests, a common law fraud claim must allege a "false misrepresentation of a material fact." *Mylan Laboratories*, 357 F. Supp. 2d at 321. As this Court has observed, a party "who disclosed partial information that may be misleading has a duty to reveal all the material facts he knows to avoid deceiving the other party." *Id.* The United States' Complaint alleges that Abbott submitted false and fraudulent prices to publications that bore no relation to the prices at which Abbott actually sold its drugs, and Abbott knew the United States relied upon the published prices to set Medicare and Medicaid reimbursements. Accordingly, the Complaint sufficiently alleges that Abbott made false statements.

Abbott argues that because the United States did not specify the exact price Abbott should have reported, Count III of the Complaint should be dismissed. The United States need

not plead one particular substitute price that Abbott should have reported to adequately plead the fraud. Regardless, Abbott started reporting market place prices in January 2001; those are the prices Abbott should have been reporting all along. Complaint at ¶¶ 83-85. Throughout the Complaint, the United States provided specific dollar amounts at which Abbott's products could be purchased and the specific fraudulently increased amount reported for use in formulas to set reimbursements.[15] In addition, the United States alleged specific evidence in the form of documents, letters and e-mails that indicate the time, place, content, and intent of Abbott's fraudulent statements. (Complaint at ¶¶ 37, 45, 63, 66, 77, 87). Thus, Abbott's motion to dismiss this claim must fail.

C. The United States Sufficiently Alleged A Claim for Unjust Enrichment

The doctrine of unjust enrichment allows for restitution when it would be unconscionable to permit another to retain the benefit received. *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 339 F. Supp. 2d 165, 181 (D. Mass. 2004); *In re Lupron Marketing and Sales Practices Litigation,* 295 F. Supp. 2d at 182. Under Massachusetts law, "[t]o satisfy the elements of unjust enrichment, a plaintiff must show: (1) an enrichment; (2) an

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[15] *See, e.g.,* Complaint at ¶ 64 ("Teena Brown represented in a letter . . . that the price of Abbott's Vancomycin . . . was . . . $58.37 a unit . . . . At the time, a customer could purchase Vancomycin . . . for $5.53 per unit . . . ."); Complaint at ¶ 81 ("[I]n 1999 Abbott's Vancomycin . . . was widely available for approximately $4.75 a unit. Yet, Abbott reported a per-unit Vancomycin DP in 1999 . . . to First DataBank of $64.35."). In addition, the United States supplied an exhibit to the Complaint which provided the specific AWPs reported in the price publications, the actual prices at which Abbott's drugs could be purchased, and the spread between these prices. Complaint, Ex. 1. The publications calculated the published AWPs by a applying a markup of, generally, 18.75% to the DPs reported directly from Abbott. Complaint at ¶ 60. Given this formulaic approach, the price spread indicated in the exhibit should have been approximately 18.75% for each of Abbott's drugs; instead it ranged from 275.71% to 1716.40%. Complaint, Ex. 1.

impoverishment; (3) a relation between the enrichment and the impoverishment; (4) an absence of justification and (5) the absence of a remedy by law." *Mylan,* 357 F. Supp. 2d at 324.

Abbott argues that because this claim is based on Abbott's wrongful actions as set out in Counts 1, 2, and 4 of the Complaint and not an independent claim, there can be no action for unjust enrichment. Memorandum of Law at 25. However, this Court has already held to the contrary in this case: "courts will look to see if a benefit has been conferred on the defendant under mistake of fact or law, if the benefit still remains with the defendant, if there has been otherwise a change of position by the defendant, *and* whether the defendant's conduct was tortious or *fraudulent*." *In re Average Wholesale Price Litigation*, 339 F. Supp. 2d at 181 (emphasis added). Under this standard, the claim must stand because Abbott did in fact benefit from reporting false prices by increasing its market position. In 1991, less than 10% of Abbott's Vancomycin sales were reimbursed by Medicaid; this amount increased to roughly 70% by 2000. Complaint at ¶ 74. The relation between this increased market share and Abbott's fraudulent reporting of prices is evidenced by Abbott documents, which show consideration by Abbott employees of the additional profits that could be obtained by artificially inflating prices. Complaint at ¶ 77. While Abbott profited from this fraudulent price reporting from 1989 through 2001, Medicare and Medicaid paid an excess of $75 million for Vancomycin alone and another $100 million for large volume parenterals. Complaint at ¶¶ 69,101. The payments from the government flowed to Abbott's customers, who in turn paid Abbott for the drugs, increasing Abbott's market share.

Abbott again attempts to argue here that it cannot be penalized for its false price reporting because the Medicare program sets reimbursement using a median AWP. The extent to which

Abbott's false price reporting affected Medicare's median reimbursement amount for Abbott's drugs is a question of fact, not one that can be disposed of on a motion to dismiss. Further, it is an issue that is relevant to damages, not liability. Furthermore, it is clear that Abbott's goal in reporting false prices was to increase overall sales. The inflated reimbursement that Abbott knew would arrive via the Medicaid program also ensured that customers bought Abbott drugs to service Medicare patients, even if Abbott could not predict in advance the amount of Medicare reimbursement for its drugs. Finally, Abbott argues that since the government would have had to pay somebody for the drugs, the government was not harmed by Abbott's fraud. The essence of unjust enrichment, however, is taking back the benefit bestowed upon an undeserving party. Here, Abbott effectively sought to secure business away from competitors by its fraudulent conduct and should not be permitted to retain the benefit of that business. Whether or not and how much the United States would have had to pay another manufacturer is legally irrelevant.

D. The FCA and Common Law Fraud Counts Are Pled With Particularity.

After spending 27 pages setting forth detailed arguments attacking the United States' Complaint, Abbott ends its Memorandum of Law by declaring that the United States' claims are too "nebulous" to defend against.[16] The purpose of Rule 9(b) is to "*give notice* to defendants of the plaintiffs' claim, to protect defendants whose reputation may be harmed by meritless claims of fraud, to discourage 'strike suits,' and to prevent the filing of suits that simply hope to uncover relevant information during discovery." *Doyle v. Hasbro, Inc.*, 103 F.3d 186, 194 (1st Cir. 1996) (emphasis added); *see also New England Data Services, Inc. v. Becker*, 829 F.2d 286, 288 (1st

[16] In addition to its detailed motion to dismiss arguments, Abbott has already propounded five hundred and one (501) discovery requests on the government regarding the allegations in the Complaint.

Cir. 1987); *McGinty v. Beranger Volkswagen, Inc*., 633 F.2d 226, 228-229 (1st Cir. 1980); *Simcox v. San Juan Shipyard, Inc*., 754 F.2d 430, 440 (1st Cir. 1985); *Hayduk v. Lanna*, 775 F.2d 441, 443 (1st Cir. 1985).

The Complaint provides ample fair notice of the United States' claims.[17] The scheme set forth in the Complaint is simple and clear: Abbott reported false prices to pricing compendia relied upon by Medicaid and Medicare to inflate reimbursements for its products. Complaint ¶¶ 3-5, 51-101, Ex. 1. The claims at issue are all Medicaid and Medicare claims submitted for the Abbott drugs or the J-Codes identified in the Complaint. Complaint ¶¶ 31-37, 58. The Complaint describes how Abbott's false price reporting affected claims for payment made to the Medicare and Medicaid programs and alleges false claims were submitted to the Government. Complaint ¶¶ 31-50. The Complaint identifies the Abbott drugs at issue and the Medicare J-Codes affected by the false price reporting. Complaint ¶¶ 31, 35. The Complaint sets forth the time period during which claims were submitted to the Medicare and Medicaid programs for the Abbott drugs identified in the Complaint. Complaint ¶ 51.

In this Circuit, an FCA plaintiff is required to plead both a fraudulent scheme and that false claims were indeed submitted. *Karvelas*, 360 F.3d at 232. The United States has done that. Abbott cites *Karvelas* and *United States ex rel. Clausen v. Lab. Corp. Of America*, 290 F.3d 1301 (11th Cir. 2002) for the proposition that to survive Rule 9(b) the United States must plead

[17] Abbott is no stranger to the allegations in the United States' Complaint, having been investigated and sued for similar conduct in other cases. As discussed earlier, its joint venture TAP Pharmaceuticals, pled guilty and reached a global settlement in 2001 to resolve its criminal and civil liability, in part for inflating the reported AWPs and marketing the resulting spread for the cancer drug Lupron. In addition, it has been sued at least 16 times since then for the same conduct set forth in the United States' Complaint.

every single detail about every single claim that was submitted to the Medicare or Medicaid programs for every one of Abbott's drugs covered by the United States' Complaint. Memorandum of Law at 29.

Abbott misapprehends the holding of these cases for several reasons. *First*, these cases involved relators – not the United States – who failed to plead the filing of a claim. *See Karvelas*, 360 F.3d at 234; *Clausen*, 290 F.3d at 1311. *Second*, neither of these Courts required the relator to plead the kind of minutiae that Abbott demands here. As the 11th Circuit clarified in *United States ex rel. Walker v. R&F Properties, Inc.*, 433 F.3d 1349 (11th Cir. 2005), the *Clausen* decision set forth a non-mandatory list of claims-related information it was looking for because the relator was a "corporate outsider" who was speculating that actual claims were submitted. *Id.* 433 F.3d at 1360; *see also Corsello v. Lincare*, 428 F.3d 1008, 1013 (11th Cir. 2005); *United States ex rel. Hill v. Morehouse Medical Associates, Inc.* 2003 WL 22019936 at *4-5 (11th Cir. August 15, 2003) (relator with firsthand knowledge of submission of claims not required to plead exhaustive claims details due her inherent factual credibility). The Courts in *Karvelas* and *Clausen* were concerned with whether there is some "indicia of reliability" to the relator's allegation that a claim was indeed submitted. *See Clausen*, 290 F.3d at 1311.

The claims at issue here were either submitted to the United States or submitted to states (many of whom have sued Abbott for this same conduct) through the Medicaid program, which were partially reimbursed by the United States.[18] The United States is not an outsider to the issue

[18] Unlike situations in which a company's fraudulent conduct likely resulted in *some* false claims but the complaint failed to specify which claims were false, *see, e.g., United States ex rel. Rost v. Pfizer, Inc. et al.*, No. 03-11084-JLT, Slip Op. at 36 (D. Mass. Aug. 30, 2006) (Tauro, J.), Abbott's manipulation of the spread of the covered drugs affected reimbursement for *every* claim submitted for those drugs; accordingly, the United States' Complaint, which alleges with

of whether claims were submitted to the Medicare and Medicaid programs and is not required to provide the information Abbott demands prior to commencing its suit. The United States is a reliable source as to whether the claims at issue were submitted.

III. CONCLUSION

For the reasons set forth above, the United States respectfully requests that the Court deny Abbott's Motion to Dismiss.

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specificity that *all* claims submitted for the covered drugs were false, satisfies the requirements of Rule 9(b).

Respectfully submitted,

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Dated: September 15, 2006

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the above **UNITED STATES' OPPOSITION TO ABBOTT LABORATORIES, INC.'S MOTION TO DISMISS** to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Gejaa T. Gobena

Dated: September 15, 2006 Gejaa T. Gobena